

# EXHIBIT U

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In Re:  
Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions MDL No.  
15-2666 (JNE/FLM)  
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VIDEOTAPED DEPOSITION

OF

MARK ALBRECHT

VOLUME 1

Minneapolis, Minnesota

Friday, October 7th, 2016  
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Reported by:  
Amy L. Larson, RPR  
Job No. 112502

## APPEARANCES:

ON BEHALF OF 3M:  
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ALSO PRESENT: Kraig Hildahl, Videographer

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Augustine Biomedical & Design  
Research and Development Report  
Dated 9/14/07

Bates AUGUSTINE\_0001577 - AUGUSTINE\_0001588

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Hastings Ventilation Assessment

Bates AUGUSTINE\_0010948 - AUGUSTINE\_0010952

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Augustine Biomedical & Design  
Research and Development Report  
Dated 10/12/2007

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Forced-Air Warming: A Source of Airborne  
Contamination in the Operating Room?  
No Bates

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Forced-Air Warming Design:  
Evaluation of Intake Filtration, Internal  
Microbial Buildup, and Airborne-Contamination  
Emissions  
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Forced-Air Warming Blowers: An  
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Patient Warming Excess Heat: The Effects  
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Effect of Forced-Air Warming on the  
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Flow Ventilation  
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Exhibit 11.....144

Data  
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Exhibit 12.....160

May 2012 E-mail Chain  
Subject: Further Infection Data  
Bates Albrecht\_0003579 - Albrecht\_0003580,  
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HotDog Patient Warming Website Screenshot  
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Color Photograph  
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## ALBRECHT

## THE VIDEOTAPED DEPOSITION OF MARK ALBRECHT,

VOLUME 1, taken on this 7th day of October, 2016,  
at the Law Offices of Blackwell, Burke, LLP,  
431 South Seventh Street, Suite 2500, Minneapolis,  
Minnesota, commencing at approximately 9:17 a.m.

## P R O C E E D I N G S

THE VIDEOGRAPHER: This is the  
start of tape labeled number 1 in the  
videotaped deposition of Mark Albrecht in the  
matter of In Re: Bair Hugger Forced Air  
Warming Products Liability Litigation, in the  
U.S. District Court, District of Minnesota.  
The MDL case number is 15-2666 (JNE/FLN).

This deposition is being held at  
Blackwell, Burke law firm in Minneapolis,  
Minnesota on October 7th, 2016. The time is  
9:18 a.m. My name is Kraig Hildahl, I'm a  
legal video specialist from TSG Reporting.  
The court reporter is Amy Larson also with  
TSG Reporting.

Will counsel please introduce  
themselves for the record.

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Q. That -- and it's your study that's cited there, right?

A. Uh-huh.

Q. Do you -- you said people can do what they want with the data, but do you think that what you see here in Exhibit 13 is scientifically supported by your study?

A. In an observational sense, yes, it is, those are the numbers for the periods. This isn't the result of a randomized clinical trial. I don't know what constitutes sufficient data for marketing. A lot of people use data in different ways.

Q. Can you -- do you believe your study can in any way be used to support the conclusion that switching from Bair Hugger to HotDog will reduce surgical site infections?

MR. B. GORDON: Objection to form, asked and answered, calls for a medical conclusion.

THE WITNESS: There's observational data in here that shows a decrease in infection rates with the switch between devices, that is true, that is

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confounded with antibiotics.

BY MR. C. GORDON:

Q. It's also confounded with prophylaxis -- thromboprophylaxis?

A. Yes. It's observational in nature.

Q. And if you eliminate just those two confounders, there is no statistical -- statistically meaningful difference --

MR. B. GORDON: Objection to form.

BY MR. C. GORDON:

Q. -- between Bair Hugger and HotDog, right?

A. This is not a randomized clinical trial. I don't know what effect led to what.

MR. B. GORDON: Object to form, misstates his testimony.

THE WITNESS: This is observational data.

BY MR. C. GORDON:

Q. Why do observational data? What's -- what's the purpose?

A. It's to identify trends that you may suspect in the data and bring it to question so someone can do a proper experiment further on, like a randomized trial.

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Q. Your trendline was just an arithmetic mean across 23 months --

A. Uh-huh.

Q. -- right?

What -- having gone through the exercise that you've gone through now to compare one time period, just the Rivaroxaban versus the no Rivaroxaban, would you agree that a trendline that shows an arithmetic mean across the -- that entire time period is pretty misleading?

MR. B. GORDON: Objection to form.

THE WITNESS: I would have liked to have added that to the effects here so it's more clear what that did over the time period. Having you make me drill into it a little more clearly like that and not treat it as just a confounder that, well, it's there, so you can't truly trust this, you know, I would have dug in a little deeper and put an effect in the table, I think.

BY MR. C. GORDON:

Q. And if you had done that, tell me what -- would that -- would you have been able to do

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a multivariate analysis with that, is that the right term?

A. I still don't think we would have. I think we would have presented it that we looked for this effect, saw nothing, we looked for that effect, saw nothing, oh, antibiotics had an effect, forced air had an effect, now we need to figure this out with a trial.

So you'd do this in a univariate fashion still with observational data, in my opinion.

Q. If you were to analyze the data factor -- taking into consideration antibiotics and the -- the Rivaroxaban, and -- and, in effect, factored those out, do you still think that there would -- even with observational data it would show a difference between Bair Hugger and HotDog?

MR. B. GORDON: Objection to form, misstates his earlier testimony.

THE WITNESS: I don't know. I would have to run a model. There's a period of time here which comes into play. This data, there's possibly not enough

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infections -- infections to do a multivariate analysis like that where it's properly powered, just kind of looking at this. I'm not so sure we'd be able to tease out the effect of multiple factors at the same time with a data set that has, you know, few infections like that over multiple cuts of variables. So that can be difficult. You'd have to try.

BY MR. C. GORDON:

Q. Well, you'd agree with me that what we just teased out with just those two -- two variables, the antibiotics and the anti-thrombophylaxis -- thromboprophylaxis, resulted in two periods that were pretty comparable in both in duration and in number of procedures, right?

A. Yeah. I'd like to add that to a table as a univariate effect and do further experimentation to see what led to what.

Q. One of my associates grew up in California.

A. Sure.

Q. And in his -- his fond young -- young childhood memory is his family going to

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Disneyland and his brother leaning over to him as they were driving to Disneyland and said, "Everybody who goes to Disneyland dies."

A. Okay.

Q. That's actually true, right?

A. All right. How is that relevant to this?

MR. B. GORDON: Object to the form of the question.

BY MR. C. GORDON:

Q. Well, you'd agree that it would be absurd to conclude from the fact that everybody who goes to Disneyland dies, that Disneyland has anything to do with people dying?

MR. B. GORDON: Object to form, calls for speculation, improper hypothetical.

THE WITNESS: I can't tell you from observational data if it's in change in device or if it's a change in antibiotics clearly, because other things are going on behind the scenes. This is a hypothesis. It's presented as such that there are these factors and if you compare the data in the way presented from here to here, you get that

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effect.

I agree that an antibiotic effect would be nice to add to this graph and help explain the challenge a little more clearly that we're facing here.

BY MR. C. GORDON:

Q. Well, not just the antibiotic fact, but the anti-thromboprophylaxis fact, right?

MR. B. GORDON: That's just blood thinner.

THE WITNESS: Yeah. And a clinician would have to tell you what's relevant. I mean, you could put a lot of things in here too and say, Well, Larry was mopping the floors in this room for these days and that, and you can make this data so high dimensional you'll find all sorts of things that relate.

But I agree that the antibiotic piece is a real thing and some kind of an effect here, univariate effect presented in the same way as the other effects would be nice to have.

BY MR. C. GORDON:

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Q. Were you ever made aware that at the beginning of the Bair Hugger period the laminar airflow system in one of the Wansbeck operating theaters was not functioning properly?

A. Not that I recall. I may have or may not, I don't know.

Q. Were you ever made aware of the fact that in 2008 and 2009 the Northumbria Trusts were repeatedly advised by the National Health Service that their SSI rates for orthopedic procedures made them a high outlier compared to other trusts in the -- in the UK?

A. I had heard they were having infection problems, I was not sure of the details.

Q. Did anyone ever tell you that as a result of those infection problems, they instituted a wide range of infection controlled procedures?

MR. B. GORDON: Object to form, lack of foundation, calls for speculation.

THE WITNESS: No, I don't know the exact procedures they implemented.

BY MR. C. GORDON: